The inventory/capacity trade-off with respect to the quality processes in a Guaranteed Service Vaccine Supply Chain

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Vaccine manufacturing supply chains are characterized by long lead times which may exceed 300 days. Such long lead times make it challenging to guarantee on-time deliveries. The long lead times are determined by the high-volume manufacturing processes (formulation, filling and packaging), but they are especially the result of the stringent quality control and quality assurance procedures. For vaccine manufacturing, the touch time is only 5 to 10% of the total lead time which indicates that it is worthwhile to study the impact of capacity on the lead times of the quality processes into more detail. For such supply chain stages, these long lead times are partly due to limited capacity in terms of laboratory equipment as well as skilled people.

The Quality Control (QC) and Quality Assurance (QA) department guarantees persistence of quality during these processes by various tests. To continue the manufacturing processes (formulation, filling and packaging), some critical tests (e.g. sterility tests) need to be performed immediately after the formulation and filling stages to identify whether the vaccines are allowed to proceed to the next stage. When the results of these critical tests are positive, the vaccines are put in a restricted status and may proceed to the next manufacturing stage. The other quality requirements, the QC and QA, are performed in parallel with the subsequent manufacturing stages as the lead times of these quality stages can be long. Each QC/QA stage (for formulation, filling and packaging) can be decomposed into four independent processes:

1. Actual quality testing of the product

2. Investigation of deviations in the actual testing (e.g. due to the calibration of laboratory instruments)

3. Document review of the production activities

4. Request for Process Change: post-approval regulatory process to change the manufacturing process according to customers' requirements. Such changes may include changes to the vaccine composition, quality control, equipment, facilities or product labelling information after a vaccine has been approved

Queuing networks and the Guaranteed Service Approach (GSA) are two well established modeling methodologies. However, as both models include nonlinear effects, Lemmens et al. (2016) mention that the direct impact of the capacity on the GSA's resulting stock levels is particularly cumbersome to derive with a resulting closed-form expression. To integrate both models, Lemmens et al. (2016) demonstrate the following three steps to embed capacity into the Guaranteed Service Approach with Variable lead times (GSA-VAR):

1. Calculate the average and variance of the lead time using batch queuing networks

2. Characterize the entire lead time distribution

3. Extend the lead time information obtained in previous steps into the GSA-VAR (Humair et al. (2013))

In this work, step 1 will be replaced with an approximate queuing methodology to calculate the average and variance of the lead time of two capacity-dependent quality process nodes: the investigation of deviations for formulation and filling. In this way, we study the impact of adding different capacity levels to these quality processes on the total lead time and different types of stock.

Acknowledgement

We gratefully acknowledge financial support from the GlaxoSmithKline Vaccines Research Chair on Operations Management and Re-Design of Healthcare Supply Chains in Developing Countries to increase Access to Medicines. GLAXOSMITHKLINE, GSK and the GSK Logo are trade marks of the GSK group of companies and are used with the permission of GSK.

References

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